Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison effect of two implemented sedation methods (Scale & protocol) by nurses on some consequences of mechanical ventilation in intensive care patients

Protocol summary

Summary

This study will implement with aim survey effect of two sedation method (Protocol and Scale) on some consequences of mechanical ventilation in patients who are under mechanical ventilation in ICU ward. inclusion criteria: age above18y and under 65y; under mechanical ventilation with Positive pressure; attachment to mechanical ventilation more than 48h; need to sedative drugs in treatment plan. exclusion criteria: Tracheostomy; weaning before 24h; using neuromuscular blocker drugs; pneumonia before 48h of attchment to mechanical ventilation. population is including all of patients under mechanical ventilation in Alzahra's Hospital in Isfahan, Iran and sample size is 25 patients of them in each group. intervention is including use of Richmond Scale and researchers made Protocol on some of the consequences of mechanical ventilation such as pneumonia, mechanical ventilation duration, ventilator mode and etc.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201098665N1**
Registration date: **2012-07-04, 1391/04/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-07-04, 1391/04/14

Registrant information

Name

Hassan Babamohamadi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research deputy of Semnan University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-04-20, 1392/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of two implemented sedation methods (Scale & protocol) by nurses on some consequences of mechanical ventilation in intensive care patients

Public title

Comparison effect of two implemented sedation methods (Scale & protocol) by nurses on some consequences of mechanical ventilation in intensive care patients

Purpose

Health service research

Inclusion/Exclusion criteria

inclusion criteria: age above18y and under 65y; under mechanical ventilation with Positive pressure; attachment to mechanical ventilation more than 48h;

need to sedative drugs in treatment plan. exclusion criteria: Tracheostomy; weaning before 24h; using neuromuscular blocker drugs; after CPR; severe hearing loss; pripheral nervous system disorders; addiction; pneumonia before 48h of attchment to mechanical ventilation.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Semnan University of Medical Sciences

Street address
Semnan- Basidj Bolv- Central deputy of Semnan University of Medical Sciences- Research and Technology deputy

City
Semnan

Postal code

Approval date
2012-06-19, 1391/03/30

Ethics committee reference number
91/186190

Health conditions studied

1

Description of health condition studied
pneumonia due to mechanical ventilation

ICD-10 code
j18

ICD-10 code description
Pneumonia, organism unspecified

2

Description of health condition studied
mechanical ventilation duration

ICD-10 code
j70.9

ICD-10 code description
Respiratory conditions due to unspecified external agent

3

Description of health condition studied
intra tracheal tube duration

ICD-10 code
y65.8

ICD-10 code description
Other specified misadventures during surgical and medical care

4

Description of health condition studied
time each of mechanical ventilation mode

ICD-10 code
z51.8

ICD-10 code description
Other specified medical care

Primary outcomes

1

Description
clinical pneumonia due to mechanical ventilation

Timepoint
first and fourth day of admission

Method of measurement
physician diagnosis

Secondary outcomes

1

Description
mechanical ventilation duration

Timepoint
hour

Method of measurement
from attchment to ventilator until weaning time

2

Description
hospitalization time in ICU

Timepoint
hour

Method of measurement
from admission in ICU until discharge time

3

Description
intra tracheal tube duration

Timepoint
hour
Method of measurement
from insertion tracheal tube until exiting

4

Description
mechanical ventilation modes
Timepoint
hour
Method of measurement
including Spont, SIMV, Bilevel

Intervention groups

1

Description
after finishing control group sampling, randomly in one section of ICU ward of Alzahra Hospital of Isfahan implement scale and in another part protocol. it is noticeable that selection of patients are based on empty bed not another factors. for elimination of effect of scale use for sedation preparation, scale group is considered. Nursing in scale group based on physician order inject sedation drugs similar to routine group but scale is available for them to use. In this group, sedation score of each patients measured by Richmond scale every 3 hours and then based on score, and physician order, nurse inject sedation drug. Researcher educate Richmond scale to nurses of wards to nurses inject sedation drugs based on scale. Also scale is attaching to wall of patients rooms for observation. Richmond scores of patients document by nurses every 3h. Allocation of patients in this group is randomly and based on inclusion criteria. in this group similar to control group physician order is base for drug prescription and followup is continued till attachgment to ventilator or having endotracheal tube, and if done tracheostomy, followup terminate.
Category
Treatment - Drugs

2

Description
at first for determination of routine method effect on outcomes of mechanical ventilation, patients who have inclusion criteria are selected as samples and is done parameteres. at current ways that is done for sadation of patients is including prescription of sedation drugs according to type, dosage, and injection via PRN method as physician order. in routine method, we use of fentanyl and morphine and midazolam via blous and PRN. these drugs is used without any scales and evaluation. nurses in this method have not any scheduled program for drug injection and decision making are based on intuition. followup duration for patients in this group is untill having endotracheal tube and attachment to ventilator. but if patient undergo tracheostomy followup terminate. drugs dosage for this group is based on physician order and prescription by nurses.
Category
Treatment - Drugs

3

Description
In protocol group, at first agitation score of each patient measured by nurse, and if Richmond score of patient was more than zero, ventilators and other devices are assessed by nurse, and after correction of changeable causes (position ...), environment improvement, giving verbal confidence to patient, Midazolam and Fentanyl are inject. Injection of these drugs is bolus at first and based on calculated dosage for weight and time duration for each drugs in protocol that continue till obtaining relaxation namely Richmond score between 0 to -1. Then continuous infusion of drug based on patient's weight is started. Thereafter control of patient's sedation level is evaluated by nurse at q3h, and based on obtained score, continue drug dose with increase, decrease or unchanged. Goal is obtaining Richmond score between 0 to -1. If necessary to decrease or increase of drug dosage, it is done by increasing or decreasing 25% to primary dosage of drug by nurses (as infusion). Richmond scores are document q3h by nurses. Protocol was designed based on research results from 2005 to current that is according to sedation level evaluation by assessment tools with sedation prescription for achieving to optimal level of sedation that is leading to improved clinical outcomes and improved quality of treatment with sedation. This protocol is confirmed by ward physician. Education of protocol to ward nursed is done by researcher. Also protocol is attached to wall of patient's rooms for observation. Richmond scores for each patient are documented by nurses. Allocation of samples to each group is based on inclusion criteria and randomly. Drugs is including: 1) midazolam Bolus 0.05 mg/kg q5m untill richmond score 0 t0 -1 and after continous infusion of midazolam 0.03 mg/kg/hr. 2) Fentanyl bolus 1/5 microgram/kg q10m till richmond score 0 to -1 and after continous infusion of fentanyl 0.7 microgram/kg/hr. follow up duration is similar to routine and scale group till attachment to ventilator and having endotracheal tube. and if done tracheostomy for patient followup is terminate.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra's Isfahan Hospital
Full name of responsible person
Mr Abasi Dorche, Saeed
Street address
Alzahra's Isfahan Hospital, ICU ward
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Ghorbani, Raheb
Street address
Semnan, Basidj Bolv, Central complex of Semnan University Of Medical Sciences
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary

empty